FDA 510(k) Premarket Notification

K942444 3002 AEROMAX

CLEARED

Mar 10, 1995
291 days to decision

K942444 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k942444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 23, 1994
Decision date	Mar 10, 1995
Days to decision	291 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medical Industries America, Inc.**
Location	Australia 2038, AU
Contact	MARK D HEBENSTREIT
510(k) history	19 submissions · 19 cleared · 1986-2005